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How Stronger Patent Protection in India Might Affect the Behavior of Transnational Pharmaceutical Industries

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How will stronger patent rights in developing countries affect transnational corporations' behavior in and toward those countries? How will market structure and consumer welfare be affected by extending patent protection to products that could previously be freely imitated? Will research-based transnational corporations devote more resources to developing technologies relevant to needs in developing countries?

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Summary findings

To address questions about how stronger patent rights will affect India's pharmaceutical industry, Fink simulates the effects of introducing such protection — as required by the World Trade Organization Agreement on Trade-Related Intellectual Property Rights (TRIPs) — on market structure and static consumer welfare. (India must amend its current patent regime by 2005 and establish a transitional regime in the meanwhile.)

The model Fink uses accounts for the complex demand structure for pharmaceutical goods. Consumers can choose among various drugs available to treat a specific disease. And for each drug, they have a choice among various differentiated brands.

Fink calibrates the model for two groups of drugs — quinolonnes and synthetic hypotensives — using 1992 brand-level data. In both groups, a subset of all available drugs was patent-protected in Western Europe but not India, where Indian manufacturers freely imitated them.

The simulation analysis asks how the market structure for the two groups of drugs would have looked if India had granted patents for drugs. It does not take account of the fact that stronger patent protection will not apply to existing drugs and that the Indian government might be able to restrain high drug prices by imposing price controls or granting compulsory licenses.

Still, Fink concludes that if future drug discoveries are mainly new varieties of already existing therapeutic treatments, the effect of stronger patent protection is likely to be small. If newly discovered drugs are medicinal breakthroughs, however, prices may rise significantly above competitive levels and static welfare losses may be large.

If demand is highly price-elastic, as is likely in India, profits for transnational corporations are likely to be small. But if private health insurance is permitted in India, reducing the price-sensitivity of demand, patent-holders' profits could increase substantially. In light of the fact that the TRIPS Agreement strengthens patent rights in most developing countries, pharmaceutical companies may do more research on, for example, tropical diseases.

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How Stronger Patent Protection in India Might Affect the Behavior or Transnational Pharmaceutical Industries

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I. Introduction

The protection of patent rights is considered to be a critical precondition for private investment in pharmaceutical research and in the development of new drugs. The importance of patent protection in this industry can be attributed to the ease with which new chemical entities can be imitated in comparison with the large R&D outlays and long product cycles associated with research-based drugs. To put it in economic terms, new chemical entities—unless legally protected by patents—are weakly appropriable from the viewpoint of the innovating firm.

The origins of the pharmaceutical industry go back to the commercialization of the first research-based drugs, Prontosil and Penicillin, in the 1930s. Since the 1960s, the development and production of pharmaceuticals has been dominated by a limited number of transnational corporations (TNCs) from developed countries (mostly from the United States, Germany, the United Kingdom, Switzerland, France, and Japan). Despite the escalating costs of R&D, a declining rate of new drug development, the expiry of patents on many blockbuster drugs in the late 1980s, and the squeezing of public health budgets, the composition of the global pharmaceutical industry has largely remained the same up to the early 1990s (Tarabusi, 1993).[1] Pharmaceutical companies have extensive international production systems. U.S. pharmaceutical TNCs, for example, have, on average, 33.8 foreign affiliates per parent firm—a larger number than in any other U.S. manufacturing industry (Maskus, 1998). This pattern fits well into the ownership-location-internalization framework (OLI) of international production: TNCs are firms with significant knowledge-based assets—patents, trademarks, and marketing expertise in the case of the pharmaceutical industry—which are internationally often most profitably exploited by taking a direct investment position in a foreign country (Dunning, 1979 and 1981).

This paper examines the impact of patent protection on the behavior of pharmaceutical TNCs and market structure in India, which has traditionally been a fierce opponent of stronger intellectual property rights. The Indian Patents Act of 1970 specifically excludes patent coverage

[1] Starting in the late 1980s, the new research tools unleashed by the science of molecular genetics have fundamentally altered the pharmaceutical R&D process and have provoked a large number of mergers and buy-outs, thus changing the traditional picture of the industry.

for pharmaceutical products. To meet its obligations under the Agreement on Trade Related Intellectual Property Rights (TRIPS)—one of the outcomes of the Uruguay trade round (1986-94)—India will have to amend its patent laws to allow for pharmaceutical product patents by 2005. The signing of the TRIPS Agreement by the Indian Government has been accompanied by forceful publicity predicting that stronger patent rights will lead to soaring prices for pharmaceuticals and to a dominance of TNCs by 'wiping-out' Indian firms. This study is intended to shed some light on these issues and may also serve as a reference point for other developing countries introducing pharmaceutical product patents in a 'post-TRIPS' world.

The method of analysis is the calibration of a theoretical model to actual data from the Indian pharmacy market and a simulation exercise to answer the hypothetical question of what the market structure would be if India allowed patents for pharmaceutical products. This technique is in the same spirit as the studies by Baldwin and Krugman (1988) on the U.S. and Japanese semiconductor industries and by Dixit (1988) on the U.S. and Japanese automobile industries, which focus on the simulation of alternative trade policy regimes.

The model developed for the simulation analysis explicitly accounts for the complex demand structure for pharmaceutical goods that results from the presence of therapeutic substitute drugs and the practice of drug manufacturers to differentiate their products through the use of trademarks and advertising. Consumer demand is represented by a three-level utility function, whereby preferences for different chemical entities and brands are characterized by constant-elasticity-of-substitution functions. In the absence of patent protection, firms are assumed to maximize profits taking as constant the sales of other market participants. If patents are protected, the patent holder has a monopoly for the chemical entity, but still competes with producers of therapeutic substitutes.

This model is calibrated for two therapeutic groups—quinolonnes and synthetic hypotensives—using 1992 brand-level data for each chemical entity sold in the two therapeutic groups which would have received patent protection in Europe (referred to as 'on-patent' chemical entities throughout this study), as well as brand-level data for all 'off-patent' chemical entities in these two groups. The simulations reveal to what extent price increases, profits, and

static consumer welfare losses depend on the values of the model's parameters and provide valuable insights with regard to the role of competition among therapeutic substances.

The paper is organized as follows. Section II briefly reviews India's current patent regime and its obligations under the TRIPS Agreement with respect to pharmaceutical processes and products. Based on this review, Section III describes the development of India's pharmaceutical industry and outlines the industry's main features. Accounting for these features, Section IV develops a partial equilibrium model of the Indian pharmacy market by specifying demand and supply behavior of consumers and producers of drugs. Section V describes the brand-level data used for the empirical investigation. Section VI explains how the partial-equilibrium model is calibrated to these data. Section VII illustrates the simulation procedure and Section VIII discusses the simulation results. Section IX summarizes the paper's main findings and puts these findings into perspective.

II. India's patent regime

The Indian Patents Act of 1970

The Indian patent system is governed by the Indian Patents Act of 1970 (which became effective in 1972). It specifically excludes patent coverage for pharmaceutical products and only admits process patents for a period of 7 years (or five years from the date of sealing the patent, whichever is shorter). With respect to process patents, there are four provisions which substantially limit the scope of protection. First, after three years from the date of sealing a pharmaceutical process patent, the 'License of Rights' clause applies. Under this clause, the patent owner is obliged to license the patented process to any interested party, with a maximum royalty of 4 percent payable by the licensee. Second, after three years from the date of sealing a pharmaceutical patent, the government can grant a compulsory license, if the patented product is not available at 'reasonable' prices or other public interests are not satisfied. The terms of a compulsory license are set by the government, unless the patent owner and licensee find agreement between themselves. Third, a patented pharmaceutical process must be worked in India within three years from the date of sealing the patent. Importation of a drug produced with

the patented process is not considered as working the patent. Fourth, the burden of proof in case of patent infringement rests with the patent owner.

In essence, the India Patents Act gives only very limited protection to research-based pharmaceutical companies. Imitating firms only have to avoid patented processes to copy a newly developed drug. It is, however, in most cases very easy to modify or circumvent a patented process in order to avoid infringement. Without product patents, protection of new drugs is very limited. Moreover, because of the various restrictions related to process patents outlined above, protection is even further reduced.[2]

The TRIPS Agreement

Patent protection in the Indian pharmaceutical industry is bound to be revised. India, as a member of the World Trade Organization (WTO), has to comply with the provisions set forth in the TRIPS Agreement.[3] The main provisions of TRIPS as they relate to pharmaceutical patents can be summarized as follows. Among the general obligations, Articles 3 and 4 of TRIPS require member governments to apply the principles of national treatment, i.e. equal treatment of nationals and non-nationals, and most-favored-nation (MFN) treatment, i.e. equal treatment of foreigners regardless of their country of origin.[4] With respect to patents, Article 27.1 of TRIPS states that "[...] patents shall be available for any invention, whether products or processes, in all fields of technology [...]," which clearly encompasses pharmaceutical products. Moreover, "[...] patents shall be available [...] whether products are imported or locally produced," which means that importation counts as working the patent. Article 31 addresses the use of patented subject matter without the authorization of the rights holder, e.g., through compulsory licenses. Although it ties such unauthorized use to specific conditions, legal interpretations of Article 31 vary and it has been argued that national governments have some leeway in designing rules regulating the

[2] In fact, most pharmaceutical TNCs have not applied for process patents in India. Redwood (1994) reports evidence that of the 20 pharmaceutical process patents filed in China, only one was filed in India. Poor patent administration in India has most likely contributed to this difference.

[3] The text of the TRIPS Agreement is available at the web-site of the World Trade Organization at <http://www.wto.org>.

[4] It should be noted that national and most-favored-nation treatment must be extended only to other members of the World Trade Organization.

grant of compulsory licenses (Watal, 1998b). Article 33 sets a uniform minimum term of patent protection of 20 years counted from the filing date. Article 34.1 specifies that the burden of proof in case of process patent infringement rests with the defendant, i.e. the party accused of patent infringement. Finally, Article 41.1 requires member governments to "[...] ensure that enforcement procedures [...] are available under their national laws so as to permit effective action against any act of infringement of intellectual property rights [...]" and Article 62.2 obligates members to "[...] ensure that the procedures for grant or registration [...] permit the granting or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection."[5]

The provisions of TRIPS became applicable to all signatories by the beginning of 1996. However, Articles 65.2 and 65.4 of the TRIPS Agreement entitle developing countries to a four-year transition period in implementing all obligations (except for obligations pertaining to national and MFN treatment) and an additional five-year transitional period for product patents in fields of technology that were not protected at the date of application of the Agreement. Accordingly, India will have to amend its patent law to allow for the grant of pharmaceutical product patents by 2005.[6] Article 70.3 does not require member countries to extend protection to subject matter in existence before the introduction of a new law, i.e. patent protection would not apply retroactively.[7] Articles 70.8 and 70.9, however, also specify that members should "[...] provide [...] a means for which patents for [pharmaceutical and agricultural chemical products] can be filed" (this 'means' is often referred to as a 'mail-box'). Moreover, for such 'mail-box' applications "[...] exclusive marketing rights shall be granted [...] for a period of five years after obtaining market approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that [...] a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member." To the extent that exclusive marketing rights related to 'mail-box' applications and

[5] Articles 42-61 of TRIPS further prescribe detailed rules and legal remedies to ensure adequate enforcement of rights.

[6] Note that an 'upgrade' of India's process patent system toward TRIPS compliance is already required by 2000.

exclusive rights conferred by a regular patent title are practically the same (Watal, 1998b), Articles 70.8 and 70.9 effectively offset the transition period with regard to pharmaceutical product patents.

Initial efforts to establish the 'mail-box' for patent applications for pharmaceutical and agricultural chemical products failed to pass the Indian legislature. Accordingly, this matter was taken to the WTO dispute settlement body by both the European Union and the United States. The WTO Appellate Board finally ruled that India has failed to take the necessary actions to implement its 'mail-box' obligations and recommended "[...] that the WTO Dispute Settlement Body requests India to bring its transitional regime for patent protection of pharmaceutical [...] products into conformity with its obligations under the TRIPS Agreement."[8] Consequently, new legislation to establish the 'mail-box' facility was passed by the Indian Parliament in early 1999. However, a proposed amendment to the 1970 Patents Act to extend patent protection to pharmaceutical products has, so far, failed to pass the legislature.

III. Industry structure

One of the stated objectives of the Indian Patents Act of 1970 was the development of an independent Indian pharmaceutical industry. The abolition of pharmaceutical product patent protection from the inherited British colonial law was seen as the key element in advancing this objective. Looking at the pure numbers, the Indian Patents Act was a 'success'. The number of supplying firms increased from 2,237 licensed drug manufacturers in 1969-70 to an estimated 16,000 producers in 1992-93 (OPPI, 1994a). The production of drug formulations grew at an average annual rate of 14.4 percent between 1980-81 and 1992-93; the negative balance of trade

[7] Such 'past subject matter' would also include drugs not yet marketed, but already past the patent publication stage in the development pipeline in other countries.

[8] The report of the panel on the India 'mail box' dispute is available at the web-site of the World Trade Organization at <http://www.wto.org>.

in bulk drugs and drug formulation that prevailed throughout the 1970s and 1980s was turned into a trade surplus by 1990.[9]

The period 1970-1993 also saw a declining market share of TNCs in India. In 1970, Indian-owned firms held a share of only 10-20 percent of the total pharmacy market, TNCs accounted for the remaining 80-90 percent. By 1980, Indian firms and TNCs had an equal share of about 50 percent; by 1993, Indian firms had raised their share to 61 percent.[10] Redwood (1994) argues that the relative decline of TNCs in the Indian pharmacy market has been against the international trend: most other countries have seen the relative share of TNCs rise at the expense of locally owned firms.[11]

It is, of course, difficult to attribute the falling market share of TNCs directly to the abolition of product patent protection through the Indian Patents Act. Other factors may have also contributed to this trend. Investment and ownership restrictions under the Foreign Exchange Regulation Act (FERA) may have discouraged many TNCs from investing in India. Severe price controls on segments of the pharmaceutical markets may have reduced the prospects of profitability. Moreover, it is possible that low Indian prices could have leaked to other markets, either in the form of parallel imports or through price controls in foreign markets tied to reference indices of prices in other markets (such as India). These factors may have caused some TNCs to shun the Indian market. However, given the critical role of product patent protection for research-based pharmaceuticals, it seems reasonable to at least in part attribute the relative decline of TNCs to the Indian Patents Act.

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[9] In 1992-93, the production of drug formulations was valued at about US$ 2.13 billion, exports were about US$ 544 million and imports were approximately US$ 482 million. See OPPI (1994a).

[10] These numbers are taken from Redwood (1994) and are based on data from the Operations Research Group (ORG)—the same source of data underlying this study's investigation. As will be further explained in Section V, the figures do not include the unaudited Indian small company sector and the Indian government sector, including hospital and military markets. This causes a downward bias in the market shares of local firms. Redwood (1994) conjectures that, in 1993, the true market share of Indian firms was probably 70 percent. It is also worth pointing out that in 1971, only two Indian-owned firms were among the top-ten companies in the Indian market (in terms of sales value), whereas in 1992, six Indian-owned firms ranked among the top-ten. See Lanjouw (1997) and Redwood (1994).

[11] It is worth pointing out, however, that in Argentina, which only introduced pharmaceutical product patents in the 1990s, the market share of locally owned companies increased from 45 percent in 1975 to 58 percent in 1988 (Fundación de Investigaciones Económicas Latinoamericanas, 1990).

This proposition is supported by the fact that the imitation and production of drugs protected by patents in other countries has indeed been a widespread activity among Indian-owned firms. Redwood (1994) estimates that 20 percent of the brands marketed by the 15 leading Indian firms in 1993 were based on chemical entities that were covered by pharmaceutical product patents in Europe and a further 37 percent were based on chemical entities of which the patent had expired somewhere between 1972 and 1993. It is worth noting that Indian firms required no formal technical assistance from abroad to produce foreign patented drugs. The published patent title provided sufficient information to imitate the newly developed chemical entity. This has been attributed to a well-developed chemical infrastructure and process skills of the local Indian pharmaceutical industry.

Copied brands of drugs patented in foreign countries have typically been introduced in the Indian market soon after the world introduction of these drugs (Lanjouw, 1997). TNCs thus did not enjoy a substantial first mover advantage in selling a newly developed drug on the Indian market. This fact has most likely contributed to the trend that many TNCs chose not to supply the Indian market in the first place. Indeed, in 1993, of the world's largest 30 pharmaceutical TNCs, only 16 had a direct investment position in India (Redwood, 1994).

Expenditure on R&D by pharmaceutical companies in India has been modest. In 1992-93, the industry spent an estimated 1.4 per cent of sales on R&D—as against 1 per cent of sales by Indian industry in general (OPPI, 1994a) and against more than 15 percent of sales by the parent groups of TNC subsidiaries (Redwood, 1994). Most R&D activity by Indian-owned firms has concentrated on imitating and adapting pharmaceutical products developed in foreign countries. Only very little R&D by Indian firms has been geared toward the development of new drugs.[12] There has been no marked difference in R&D spending between Indian-owned firms and the subsidiaries of TNCs. Foreign-owned companies relied heavily on product and process technologies supplied by their parent groups and conducted little original R&D.

Profitability in the Indian pharmaceutical industry has continuously declined from an estimated 15.5 percent of sales (before tax) in 1969-70 to 1 percent in 1991-92 (OPPI, 1994a).

[12] Lanjouw (1997) reports that during 1975-95 only 65 of approximately 100,000 U.S. patents related to drug and health innovations were granted to Indian inventors.

Redwood (1994) reports evidence from a sample of Indian and foreign-owned companies which suggests that profitability has been higher for pharmaceutical exports, but confirms that in the early 1990s, home sales of pharmaceutical companies in India were doing little better than breaking even. Moreover, Redwood finds no marked difference between the profitability of Indian firms and foreign-owned companies.

The absence of patent protection for pharmaceutical products, the large number of supplying units, the low degree of profitability, and very low drug prices in India by 'international standards' could be taken as an indication for a highly competitive market. While this seems a plausible scenario, one should be careful in drawing premature conclusions solely based on these descriptive indicators. There are many well-known problems related to the comparison of prices from different countries quoted in different currencies.[13] In addition, not all market participants directly compete with each other. The market for antibiotics, for example, can be considered as being independent of the market for, say, cardiovasculars. Competition is limited to a group of drugs that are therapeutic substitutes for each other. Finally, pharmaceutical companies in India, as in developed countries, differentiate their products through trademarks and promote their brands through advertising, thus generating market power even though a large number of other brands of the same drug may be available (Lanjouw, 1997). The model developed in the next section accounts for these special features of the pharmaceutical industry.

IV. The model setup

Several studies are available that simulate the impact of patent protection on prices and welfare in developing countries' pharmaceutical industries (Nogués 1993, Maskus and Konan, 1994, and Subramanian, 1995). These studies rely on aggregate data on the patent protected segment of the pharmaceutical market and simulate the transition toward a patent-induced monopoly by making various assumptions on the pre-patent market structure and market

[13] One popular and often-cited comparison of drug prices has been between India and Pakistan. Keayla (1994), for example, finds substantially higher prices in Pakistan (converted into Indian Rupees using a market exchange rate) than in India and attributes this difference to the absence of patent protection for pharmaceutical products in India. The causality is unlikely to hold in this case, however, because Pakistan also did not accept product patents during the period of comparison (Watal, 1998a).

demand.[14] However, they can only give rough estimates of the impact of patent protection as they do not take into account the independence of different therapeutic groups and the different market structures that may exist in these therapeutic groups.

Watal (1998a) improves upon these studies by using brand-level data for all on-patent chemical entities on the Indian pharmacy market and simulating the transition toward a patent-induced monopoly for each on-patent chemical entity. Brands of the same entity are assumed to be perfect substitutes and, in the absence of patent protection, market participants engage in Cournot-Nash competition. Watal's study considers both a linear and a constant elasticity demand function and links the assumed demand elasticity to the level of therapeutic competition expressed by the market share of the chemical entity in the overall therapeutic group.

Watal's simulated price increases and welfare losses are, to date, the most detailed figures available for the Indian market. However, the study's methodology can be criticized on two grounds. First, the assumption that brands of the same chemical entity are perfect substitutes seems at odds with the observed pattern of product differentiation through trademarks and advertising described in the previous section.[15] Second, the market share of a chemical entity in the overall therapeutic group may not be a good indicator of the level of therapeutic competition faced by this entity. The degree to which one drug can be substituted by another is likely to depend on the therapeutic properties of these drugs rather than on the revealed market share.

The partial equilibrium model developed in this section addresses these issues. It seeks to capture the specific features of the Indian pharmaceutical industry as described in the previous section. Market demand is modeled by a three-level utility function that accounts for therapeutic substitution and product differentiation. In the absence of patent protection, firms are assumed to maximize profits taking as constant the sales of other market participants. If patents are

[14] Nogués (1994) assumes a perfectly competitive pre-patent market structure. Maskus and Konan (1994) assume that in the absence of patents a dominant foreign-owned firm competes with a domestic fringe industry. Subramanian (1995) uses an upper bound scenario (perfect competition) and a lower bound scenario (duopoly) as alternative pre-patent market structures.

[15] In fact, in an earlier version of this paper, I tried to simulate the impact of patent protection using a model that also treated brands of the same chemical entity as perfect substitutes and assumed Cournot-Nash behavior. This approach was abandoned, because this model could only be brought into consistency with the data if one assumed unrealistically low demand elasticities.

protected, the patent holder has a monopoly for the chemical entity, but still competes with producers of therapeutic substitutes.

Demand for Drugs

Modeling the demand for pharmaceutical goods is quite a complex task. Standard economic theory assumes that the decision to purchase a good, to make the payment, and then to consume it are undertaken by one person. For pharmaceuticals, however, this is hardly ever the case. Indeed, this decision may involve as many as four different persons: the doctor, who chooses and prescribes the drug; the pharmacist, who may choose among branded or generic substitutes; the insurer, who may pay in full or for a portion of the drug; and the patient, who consumes the drug and may additionally influence the choice of drug and make partial or full payment. The details of this decision-making process vary from country to country and depend on various institutional and economic circumstances, such as the freedom of the doctor to prescribe the drug he finds most suitable for the patient, policies which may encourage generic substitution, the availability and design of health insurance plans, and the patient's income.

We model the decision to purchase a pharmaceutical good as a two-stage decision-making process as illustrated in Figure 1. First, a decision has to be made on a particular chemical entity to fight the patient's disease. This choice usually rests with the doctor who prescribes the chemical entity. Although no two different chemical entities have exactly the same effect, there are therapeutic substitutes which fight the same disease. Unless the doctor makes his decision for a particular drug on a purely medical basis, the prices of different substitutes may influence the doctor's choice of which chemical entity to prescribe. In this decision, the doctor is influenced by the patient's means. Once a particular chemical entity has been prescribed, a second decision has to be made on the particular brand supplying this chemical entity.[16] This

[16] Note that the term 'branded drug' differs in the Indian context from 'branded drugs' in developed country markets. In developed countries, a branded drug often refers to the patented product first introduced in the market. Generic drugs typically refer to copies of products of which the patent has expired. This terminology is sometimes confusing, as generic drugs may have a brand name, protected by a trademark. Because India does not protect product patents, there are only generic drugs on the market, but generic drug producers generally prefer to differentiate their products with brand names.

decision is either made by the doctor, the pharmacist, and/or the patient.[17] It is primarily influenced by the patient's budget and brand loyalty induced by marketing and advertising, as well as by past experience.

Formally, we model this two-stage decision-making process is modeled by a three-level utility function. Upper tier preferences of a representative patient are represented by a quasi-linear utility function:

$$u(X,Y) = aX^{(\varepsilon-1)/\varepsilon} + bY, \qquad a,b>0, \tag{1}$$

where X corresponds to a subutility level derived from all the chemical entities that are available to fight a particular disease, Y is a bundle of other goods and services, and a and b are functional parameters. The subutility X is determined by a constant-elasticity-of-substitution (CES) function of chemical entities in the therapeutic group:

$$X = \left[\sum_{i=1}^{n} v_i X_i^{\rho}\right]^{1/\rho}, \qquad \sum_{i=1}^{n} v_i = 1,\ \rho<1, \tag{2}$$

where X_i corresponds to a 'sub-subutility' level derived from all the brands supplying chemical entity i, n is the number of chemical entities available in the therapeutic group, v_i are distribution parameters that permit the relative importance of chemical entities to vary, and ρ is the substitution parameter. As is well known for CES functions, the elasticity of substitution σ between any pair of chemical entities is given by $\sigma = 1/(1-\rho)$. The third level of the utility function relates the sub-subutility X_i to all brands supplying chemical entity i—again using a CES function:

$$X_i = \left[\sum_{j=0}^{m_i} w_{ij} X_{ij}^{\delta_i}\right]^{1/\delta_i}, \qquad \sum_{i=0}^{m_i} w_{ij} = 1,\ \delta<1, \tag{3}$$

[17] Lanjouw (1997) reports evidence that Indian patients exhibit a strong influence on the choice of drugs and that it is generally easy to obtain prescription-only drugs without scripts.

where X_{ij} is the output of brand j for chemical entity i, $m_i + 1$ is the number of brands supplying chemical entity i, w_{ij} are distribution parameters that permit the relative importance of brands to vary, and δ_i is the substitution parameter.[18] The substitution elasticity ϕ_i between any pair of brands is given by $\phi_i = 1/(1-\delta_i)$. We would expect that $\phi_i > \sigma$, as brands of the same chemical entity are better substitutes for each other than chemical entities of a given therapeutic group.

This three-level utility function captures the fact that not only are different chemical entities imperfect substitutes for one another, but also that brands of the same chemical entity are imperfect substitutes due to experience, trademarks, and promotional activities. The model imposes four restrictions on drug preferences. First, marginal rates of substitution between any two chemical entities are independent of the quantity consumed of other goods and services. To put it differently, the consumer's upper tier preferences are separable from the preferences for chemical entities once a choice on the therapeutic group has been made. Second, marginal rates of substitution between any two brands of the same chemical entity are independent of the consumed quantity of brands of different chemical entities (separability of middle tier preferences). Third, elasticities of substitution between any two brands of the same chemical entity are the same and are constant. Fourth, the elasticity of substitution between any two chemical entities is the same and is constant. These restrictions seem mild in relation to the complexity of the overall demand structure.

Because preferences at each level are separable, we can solve the consumer's problem of maximizing the utility function implied by (1) to (3) subject to the usual budget constraint in stages. At the therapeutic group level, the quasi-linear utility function in (1) implies a constant-elasticity overall demand function:

$$D = kP^{-\varepsilon}, \qquad k = \left(\frac{b\varepsilon}{a(\varepsilon-1)}\right)^{-\varepsilon} P_Y^{\varepsilon}, \tag{4}$$

[18] As will become clear when modeling the supply side, it is convenient to introduce m_i+1 brands, as it facilitates the distinction between the patent holder's brand (brand 0) and the brands of m_i Indian imitators.

where P is a price index for the therapeutic group and P_Y is a price index of other goods and services. For the subutility function (2) and the sub-subutility function (3), maximization yields the following demand functions for a chemical entity, D_i, and for a brand, D_{ij}:[19]

$$D_i = v_i^{\sigma} D\left(\frac{P_i}{P}\right)^{-\sigma}, \tag{5}$$

$$D_{ij} = w_{ij}^{\phi} D_i\left(\frac{P_{ij}}{P_i}\right)^{-\phi_i}, \tag{6}$$

where P_i is a price index for chemical entity i, and P_{ij} is the product price for brand j of chemical entity i. Substituting (4) and (5) into (6) gives:

$$D_{ij} = w_{ij}^{\phi_i} v_i^{\sigma} k P^{\sigma-\varepsilon} P_i^{\phi_i-\sigma} P_{ij}^{-\phi_i}, \tag{7}$$

which represents the demand function perceived by a firm supplying brand j of chemical entity i.

Supply of Drugs

The production of a drug formulation typically consists of the transformation of an intermediate input in the form of one or more bulk drugs into tablet or liquid form, plus packaging and labeling. Bulk drugs are either produced in-house, purchased locally from an Indian firm, or imported from another country. There do not seem to be significant economies of scale related to the production of drug formulations (Caves, Whinston, and Hurwitz, 1991). Hence, it is assumed that drug-producing firms face constant marginal costs. This assumption is convenient, as one can ignore firms' export decisions.

Consider the market for chemical entity i in a given therapeutic group and let us initially assume that there is no patent protection for pharmaceutical products in India. There are then two types of firms that contemplate entering the market for i. The TNC, which invented the chemical

[19] For a derivation of these demand functions, see Armington (1969).

entity, supplies brand 0, while Indian imitators supply m_i competing brands. In line with actual ownership patterns (see Section V), we allow for the possibility that firms supply more than one brand of chemical entity i or brands of other chemical entities in the therapeutic group. Regarding market behavior, we assume that firms maximize profits taking as constant the sales of other market participants. The appendix shows that this leads to the first order conditions

$$P_{ij}\left(1-\frac{1-(s_{ij}+\sum_k s_{ik})}{\phi_i}-\frac{(s_{ij}+\sum_k s_{ik})(1-t_i)-\sum_l s_{l.}t_l}{\sigma}-\frac{(s_{ij}+\sum_k s_{ik})t_i+\sum_l s_{l.}t_l}{\varepsilon}\right)\leq c_{ij}, \qquad (8)$$

for $j=0,1,\ldots,m_i$ and $i=1,\ldots,n$, where

$$s_{ij}=\frac{P_{ij}D_{ij}}{\sum_{l=0}^{m_i}P_{il}D_{il}}$$

and

$$t_i=\frac{P_iD_i}{\sum_{l=1}^{n}P_lD_l}$$

are brand j's and drug i's market shares, respectively, and c_{ij} is the marginal cost of producing brand j. The index k includes all other brands of chemical entity i that are supplied by the firm that supplies brand j. Similarly, the index l includes all other chemical entities for which the firm that supplies brand j of chemical entity i produces a brand and the market share $s_{l.}$ relates to exactly this brand.

Intuitively, the second term in the bracket in (8) captures firms' recognition that they can induce consumers to switch to their brands from other brands, the third term captures the influence of therapeutic substitution on firms' sales decision, and the final term captures the impact of overall market demand on this decision.

Note that (8) holds with equality only if the output of firm j is positive. In particular, it may be that the patent owner of i is not active in the Indian market in the absence of patent protection—indeed this is the case for the drugs analyzed in this study. In this case, the model assumes that the market is served entirely by local firms and output in equilibrium is determined by competition among Indian firms only. This, in turn, assumes that the absence of the patent owner in the Indian market does not pose an obstacle to imitation of a chemical entity. As explained in the preceding section, this scenario seems to be a realistic description of the observed pattern: the patent title published abroad provides sufficient information for Indian firms to imitate a newly developed chemical entity. If an on-patent drug is not introduced in India, it is only because of low market demand and can for the purposes of this model be ignored.[20]

We assume that the TNC faces fixed cost F_{i0} to enter the Indian market for chemical entity i and all Indian firms face fixed entry costs F_{ij}. With otherwise unrestricted entry into the industry, the number of Indian firms is endogenously determined by the structure of fixed and marginal costs in the imitating industry. As pointed out in Section III, actual profitability in the Indian industry is small. This is consistent with the present model if firms' operating surpluses are largely absorbed by their fixed costs. Section VI will calibrate this model to the firm-level data from the Indian pharmacy market.

In Section VII, we will simulate the effect of patent protection by assuming that the patent holders' brands will take over the markets for all on-patent chemical entities. Setting $s_{i0} = 1$, the second term in the bracket in (8) drops out, and it is apparent that the TNC's sales decision depends only on the degree of therapeutic competition and on overall market demand. To put it differently, if patent rights are protected, the TNC has a monopoly at the level of the chemical entity, but still competes with substitute chemical entities. In contrast to the calibrated equilibrium, we will take the number of Indian firms in the off-patent market segment as exogenously given and base our simulation on the same brands and ownership patterns oberved

[20] By definition, there is no patent holder for off-patent chemical entities. In this case the market is served by Indian firms only. If a patent on a chemical entity has expired and the former patent holding TNC is active in the Indian market, this TNC can, for the purpose of this model, be treated as an Indian firm.

in the calibrated equilibrium.[21] Of course, it would have been more realistic to allow for the possibility of entry or exit in the off-patent market segment, but this was ruled out by the lack of data on the fixed cost structure among Indian firms.

V. The data

The data used for the calibration of the model developed in the previous section come from the ORG pharmacy audit of December 1992 (Operations Research Group, 1993).[22] The ORG pharmacy audit does not cover the very small company sector and sales to hospitals and the public sector (e.g., sales to the military). Watal (1996) conjectures that the unaudited share of the total pharmaceutical market is likely to be lower in India than in the United States, where it is estimated to be 11 percent. Although the basis for this conjecture is not clear, it seems reasonable to assume that the share of the pharmaceutical market unaudited by ORG is small (in any case, brand-level data for the small company sector and sales to hospitals and to the public sector were not available). Moreover, in terms of the model used in this study, the exclusion of the hospital market and government procurement may actually be an advantage, as these market segments may exhibit a different demand behavior than the one assumed in Section IV.

Redwood (1994) identifies 24 chemical entities from 13 different therapeutic groups, which were among the Top-500 pharmaceutical products on the Indian pharmaceutical market in 1993 and which were under active patent protection in Europe.[23] Using the ORG classification, the Indian Pharmaceutical Guide (1997), Drug Index (1997), and Current Index of Medical Specialities (1998), one could identify all brands/firms for each on-patent chemical entity, all off-patent therapeutic substitutes in the respective therapeutic groups, and the brands for each off-patent chemical entity. I then chose two of the 13 therapeutic groups—quinolones and synthetic

[21] Note that ownership patterns remain only unchanged as far as off-patent chemical entities are concerned. Indian firms lose, of course, ownership of brands of on-patent chemical entities in the simulated equilibrium.

[22] I would like to thank Jayashree Watal for granting me access to the ORG data.

[23] According to Redwood (1994), the Top-500 pharmaceutical products represented 67.7 percent by value of the total pharmacy market audited by ORG. Brands based on the 24 on-patent chemical entities accounted for sales of Rs 3,280 million or 10.9 percent of the total sales values of the Top-500 products in 1993.

hypotensives—for the calibration and simulation exercises.[24] The choice of these two therapeutic groups was guided by two factors. First, all chemical entities under investigation had to be free of price controls.[25] For example this led to an exclusion of Antipeptic ulcerants (with 3 on-patent chemical entities) as the prices of Ranitidine, one of the best-selling drugs on the Indian pharmacy market in 1992, were controlled (see Redwood, 1994). Second, for these two therapeutic groups, the number of (imitating) brands supplying each on-patent chemical entity was large and there was an ample number of chemical entities. Hence, the effects of patent-induced monopolies and the role of therapeutic substitution are likely to be important in the two therapeutic groups chosen.

Using the Merck Index (1989), the patent owners for each on-patent chemical entity in the two therapeutic groups was identified. In all cases, it was found that the patent owner did not supply the Indian market. The absence of the patent owner may have been due to two factors: either the title holder did indeed decide to abstain from the Indian market or the title holder was active through a licensee. Since no information could be obtained on licensing relationships, it was assumed that the patent owner decided to abstain from the Indian market.[26] This assumption, of course, could lead to a potential bias if licensing had been a widely used method of serving the Indian market for the six on-patent chemical entities. At the same time, it could be argued that potential royalties and license fees may have been small precisely because product patent protection had not been available.

For each brand name, the ORG data list total sales revenue and quantity sold, from which the brand's average market price could be computed. In two instances, it was found that

[24] In deciding which set of chemical entities constitutes a therapeutic group, the ORG classification was used.

[25] The Indian government has made wide use of Drug Price Control Orders (DPCOs) to keep prices for medicines low. Fixed price ceilings would lead to a different market behavior of drug producers than the one assumed in Section VI. Fink (1999), for example, demonstrates that price ceilings do not lead to a unique Nash equilibrium if the TNC's and imitators' goods are perfect substitutes and firms engage in Cournot competition.

[26] In the case of Quinolones, three of the four patents were owned by Japanese TNCs and several analysts have pointed out that Japanese firms decided to 'drop' the Indian market because of weak patent protection. See Redwood (1994).

one Indian firm supplied two brands of the same chemical entity.[27] In addition, there were numerous cases, in which one firm supplied two or more brands of different chemical entities, but in the same therapeutic group. Following similar studies, only the tablet form and only the most popular dosage form for each chemical entity was used (Watal, 1998a, and Caves et al., 1991). However, different package sizes (with the same dosage) were aggregated to compute a single price and the variables were expressed in single dosage units (instead of packages). Finally, figures were transformed in terms of their monthly average, since for selected cases, firms entered the market during 1992. This averaging was possible because the month of entry was listed in the ORG data. Although one ignores possible seasonal fluctuations by this procedure, it was preferred to simply excluding these market entrants.

Table 1 lists the 5 different quinolone entities, the patent owner, the year of patent expiry in Europe, the number of brands supplying the chemical entities, total annual sales, the weighted average price, and the weighted standard deviation of prices. As can be seen, four on-patent chemical entities competed with one off-patent chemical entity. The four on-patent chemical entities accounted for approximately 53 percent of the total sales value of all 24 on-patent chemical entities identified by Redwood's study. Table 2 presents the same information for the group of synthetic hypotensives. In this group, two on-patent chemical entities competed with 9 off-patent drugs. The two on-patent chemical entities accounted for 4 percent in sales of the 24 on-patent drugs identified by Redwood. Note that five off-patent entities were supplied by monopolists.

As can be seen by comparing Tables 1 and 2, the two therapeutic groups chosen represent two alternative pre-patent market structures. In the case of quinolones, the on-patent drugs dominated the market and competed with only one off-patent drug. The reverse holds for synthetic hypotensives—the on-patent drugs had a minority market share and competed with a large number of off-patent drugs.

[27] The exact strategy of supplying two brands of the same chemical entity remains a bit unclear. One possible explanation is that the two firms previously experienced mergers or acquisitions and they prefer to keep existing brands to maintain customer loyalty.

VI. Model calibration

To calibrate and simulate the model developed in Section IV, we need to have values for the elasticities ϕ_i, σ, and ε. Unfortunately, no outside estimate for any of these three elasticities was available. In principle, one could have tried to estimate values of substitution and demand elasticities econometrically, but this was ruled out by the lack of availability of time series data on prices and quantities. Moreover, one would face the standard identification problem, as data on prices and quantities are simultaneously determined by supply and demand and it would be difficult to think of effective 'supply-shifting' instruments.

The only additional information available is an estimate of firms' average profit margin. Based on pharmaceutical companies' annual reports, Redwood (1994) estimates that variable costs of firms averaged 65 percent of sales, with operating profit margins of 35 percent of sales. We therefore take the following approach. We assume two alternative values for each of the three elasticities and evaluate whether or not different combinations of these values are realistic by comparing the implied average operating margin to the 35 percent benchmark. Obviously, this approach is far from perfect, but the different assumptions on ϕ_i, σ, and ε give a reasonable indication on how sensitive the simulation results are to these parameters and on the overall magnitude of the impact of patent protection in the two therapeutic groups.

Since we expect two brands of the same chemical entity to be good substitutes for each other, we take relatively high values for the substitution elasticity among brands ($\phi_i = 3.5$ and $\phi_i = 5.5$). Note that the two alternative assumptions on ϕ_i apply to all firms in the therapeutic group. The substitution elasticity among chemical entities is assumed to be comparatively smaller ($\sigma = 1.1$ and $\sigma = 2.0$). Finally, for the overall elasticity of demand in the therapeutic group, we use a low price sensitivity assumption ($\varepsilon = 1.5$) and high price sensitivity assumption ($\varepsilon = 2.5$).[28]

[28] In India, only a small minority of the population is covered with health insurance. In 1990, 78 percent of all Indian health care spending was paid for privately (World Bank, 1993).[28] With undeveloped private health insurance plans, this implies that about three-quarters of drug expenditure are directly paid by the patients

With values for ϕ_i, σ, and ε, and the actual data on prices and market shares, we can use (8) to directly calculate firms' marginal cost of production, c_{ij}. Next, we can compute the weight parameters w_{ij} of the CES function in equation (3). From (6), it follows that

$$D_{ij} w_{ij}^{-\phi_i} P_{ij}^{\phi_i} = D_{iz} w_{iz}^{-\phi_i} P_{iz}^{\phi_i}, \qquad \text{for all } j, z\ (j \neq z),$$

which can be solved for w_{iz}. With $\sum_{z=0}^{m_i} w_{iz} = 1$, this leads to:

$$w_{ij} = \left[1 + D_{ij}^{-1/\phi_i} P_{ij}^{-1} \sum_{z \neq j} D_{iz}^{1/\phi_i} P_{iz} \right]^{-1}. \tag{9}$$

A problem is that the patent holders are not active in the calibrated equilibrium ($D_{i0} = 0$). This would lead to weights w_{i0} equal to zero—consumers do not consider consuming the TNC's product if it is not available. For the purpose of this analysis, however, preferences have to be broader and include the patent holder's product in consumer choice. Specifically, consumers must know that the patent holder's product exists and would possibly buy it, if it would be available.[29] The calibration therefore assumes that the patent holder's brand is, on average, valued 'like any other brand'. In computing the weight parameters w_{ij}, we therefore set P_{i0} equal to the weighted average price of a chemical entity and D_{i0} equal to the average firm output.[30] This approach is somewhat unsatisfactory, but there does not seem to be a good alternative.

(Redwood, 1994). One would therefore expect demand for drugs in India to be much more sensitive to price changes compared to developed countries with comprehensive health insurance coverage.

[29] Since preferences described by a CES function value variety, consumers actually suffer a utility loss through the unavailability of the patent holder's brand (see Section VIII).

[30] Note that this procedure does not change the importance of any two existing Indian brands relative to each other. The ratios of any two weight parameters w_{ij} and w_{iz} are independent of the inclusion of the patent holder's product in the preference structure.

With the obtained values for w_{ij} and equation (3), we can compute figures for the sub-subutility levels X_i. Price indices for chemical entities are given by:[31]

$$P_i = \left[\sum_{j=0}^{m_i} w_{ij}^{\phi_i} P_{ij}^{1-\phi_i} \right]^{1/(1-\phi_i)} . \tag{10}$$

Next, we calibrate the model at the level of chemical entities by taking parallel steps to the ones taken at brand level. First, the weight parameters v_i can be computed through:

$$v_i = \left[1 + D_i^{-1/\sigma} P_i^{-1} \sum_{z \neq i} D_z^{1/\sigma} P_z \right]^{-1} . \tag{11}$$

This allows us to calculate the subutility of the therapeutic group X using equation (2). The price index of the therapeutic group is given by:

$$P = \left[\sum_{i=1}^{n} v_i^{\sigma} P_i^{1-\sigma} \right]^{1/(1-\sigma)} . \tag{12}$$

Finally, with these values for the subutility level, the overall price index and the assumption on ε, we can solve for the parameter k in the overall demand function in (4).

Table 3 (for quinolones) and Table 4 (for hypotensives) present the calibrated weight parameters v_i for each chemical entity and for the alternative assumptions on ϕ_i and σ (v_i is independent of ε). It is worth pointing out that in both therapeutic groups, there are only small differences in the values of the weight parameters for the two assumptions on the substitution elasticity among brands, ϕ_i; the weight parameters are more sensitive to the assumed elasticity of substitution among chemical entities, σ.

To evaluate the plausibility of the assumed elasticities, Tables 5 and 6 present the simple average and sales-weighted average profit margin in the two therapeutic groups for each combination of the three elasticities. In the case of quinolones, this profit margin is quite

[31] For a derivation of the price index formula, see Armington (1969).

sensitive to the assumed elasticity of substitution among brands ϕ_i, but insensitive to the other two elasticities. For this chemical entity, the assumption $\phi_i = 5.5$ leads to average profit margins that lie always below the 35 percent benchmark (both on an unweighted and sales-weighted basis). Hence, the assumption $\phi_i = 3.5$ appears to be more realistic. In the case of hypotensives, a more mixed picture emerges, although average profit margins are consistently lower for $\phi_i = 5.5$ than for $\phi_i = 3.5$. Again with reference to the 35 percent benchmark, the combination of $\phi_i = 3.5$ and $\sigma = 2.0$ seems to be the most realistic for this chemical entity.

VII. Model simulation

In order to simulate the effect of 'overnight' patent protection on the two therapeutic groups analyzed, we need to have a value for the TNC's marginal cost of production c_{i0}. Because the patent holder is inactive in the calibrated equilibrium, we, again, face again the problem of requiring data about something which does not exist. We therefore assume that the TNC faces the same marginal cost as 'any other Indian firm'. Specifically, c_{i0} is taken to be the output-weighted average marginal cost of all Indian firms active in the calibrated equilibrium for the respective chemical entity. In addition, the simulation assumes that the TNC will become active once pharmaceutical patent protection is introduced.[32]

As mentioned in Section IV, we simulate the case whereby the TNC gains a monopoly for its patented chemical entity ($s_{i0} = 1$ for all on-patent chemical entities). Equilibrium values for all endogenous variables can be computed using the first order conditions in (8), the demand function (7), the formulae for the sub-subutilities (3) and subutility (2), and the price indices (10) and (12). This non-linear system of equations has no analytical solution and, therefore, has to be solved with a numerical procedure.

It is also desirable to evaluate the effect of patent protection on welfare. We concentrate on consumer welfare here, because potential changes in producer surplus are hard to evaluate without any information on Indian firms' fixed costs. In addition, although we assume a fixed

number of firms supplying off-patent chemical entities in the simulation, it is more likely that changes in market condition result in entry or exit. This claim is supported by the low actual profitability observed in the industry.

As for consumer welfare, the quasi-linear utility function in (1) implies the following indirect utility function:

$$V(P,P_Y,I)=\frac{b}{P_Y}\left[\frac{AP^{1-\varepsilon}}{\varepsilon-1}+I\right], \tag{13}$$

where I denotes overall income of patients requiring medical treatment with a drug of the therapeutic group. We can compute compensating variations, i.e. the additional income needed to make consumers as well off after patent introduction as before patent protection, by using the two different values for the price index P from the calibrated and simulated equilibria and computing the change in the term $AP^{1-\varepsilon}/(\varepsilon-1)$.[33]

VIII. Simulation results

The simulation results for the alternative assumptions on the three elasticities are presented in Table 7 for the four on-patent quinolones and in Table 8 for the two on-patent hypotensives. The tables present percentage price increases and the TNC's operating profit, which would result from overnight patent protection. Price increases are computed relative to the weighted average prices listed in Tables 1 and 2. Figures for TNC profits are on a monthly basis.[34]

As can be seen in the tables, price increases and TNC profits vary widely depending on the assumptions of demand and substitution elasticities. Several general observations can be

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[32] Theoretically, it is possible that the patent holder's monopoly profits are not sufficient to cover its fixed costs F_{i0} of doing business in India.

[33] Theoretically, it is possible that the patent holder's monopoly profits are not sufficient to cover his fixed costs F_{i0} of doing business in India.

[34] Simulation results for the off-patent chemical entities as well as figures for changes in subutility levels and price indices are suppressed, as they would add little information.

made, however. To begin with, a larger value for the substitution elasticity among brands, ϕ_i, implies larger price movements. This is due to a more competitive pre-patent market structure that prevails if brands are better substitutes for one another. The main determinant of price changes, however, is the elasticity of substitution between chemical entities, σ. For all on-patent chemical entities, the percentage price increases for $\sigma = 1.1$ exceed several times the percentage increases for $\sigma = 2.0$. This result supports the frequent claim that 'effective' competition from therapeutic substitutes limits 'excessive' prices of on-patent drugs.

For the group of quinolones, a somewhat surprising result is that, for $\sigma = 1.1$, the percentage price increases of on-patent chemical entities with a smaller number of imitating brands in the pre-patent market structure exceed those with a larger number of brands. The explanation for this result is that the drugs with the larger number of pre-patent brands also have a larger share of the therapeutic group's market. By inspection of the pricing formula (8), it follows that the patent holder's sales decision puts a relative greater emphasis on the overall demand elasticity, ε, in the therapeutic group. If $\sigma < \varepsilon$, this has a *relative* offsetting effect on the patent holder's operating profit margin vis-à-vis chemical entities with a smaller market share in the therapeutic group. It turns out that for $\sigma = 1.1$, this offsetting effect is large enough to lead to a smaller percentage price increase, despite the fact that there is a larger number of imitating brands in the pre-patent market equilibrium.

Does stronger therapeutic competition, as reflected by a larger value of σ, lower the profits of the patent holders? Not necessarily. Consider, for example, the case of ofloxacin in Table 7. For all combinations of ϕ_i and ε, profits are higher under more intense therapeutic competition ($\sigma = 2.0$). Although patent protection raises ofloxacin's price, under strong therapeutic competition it experiences increased demand as prices for other on-patent chemical entities also rise. This demand shift is due to the particular properties of the CES subutility function in (2) combined with the fact that ofloxacin was calibrated as relatively unimportant in consumer preferences, as reflected by its low values for v_i in Table 3.

But another mechanism is at work. Consider the case of ciprofloxacin in Table 7. For a demand elasticity of $\varepsilon = 2.5$, profits are higher under more intense therapeutic competition. In

this case, it cannot be due to a demand shift, as ciprofloxacin was calibrated as relatively important in consumer preferences as reflected by its high values for v_i in Table 3. Instead, lower profits are due to the 'mistakes' patent holders commit by taking other firms' sales decisions as given. In the specific case of ciprofloxacin and the assumed elasticities, the cost of this 'mistake' can outweigh the benefit of lower therapeutic competition.

In sum, a variety of forces is at work with regard to TNC profits. By comparing the simulation results for the on-patent quinolones to the results for the on-patent hypotensives, however, one can still draw a useful conclusion. If the number and weight of off-patent chemical entities is significant—as is the case for hypotensives—a higher degree of therapeutic competition is likely to lead to lower TNC profits, as demand unambiguously shifts from on-patent to off-patent chemical entities. In addition, overall profit levels depend significantly on the elasticity of demand ε. If the therapeutic group is highly sensitive to price movements ($\varepsilon = 2.5$), profits are lower than if demand is inelastic ($\varepsilon = 1.5$)—as expected.

It is interesting to use the simulation results to ask the hypothetical question: would product patent protection in India lead to accelerated R&D by TNCs and consequently to a greater rate of drug discovery (particular for the type of diseases most prevalent in low-income countries like India)? Consider again the case of ciprofloxacin and assume the more realistic $\phi_i = 3.5$. Under the most favorable circumstances, the patent owner realizes operating profits equal to 134.2 million Rs. or around US$ 5.2 million (on an annual basis).[35] In the worst case scenario, the TNC only makes profits of 17.7 million Rs. or US$ 0.7 million. Note that the TNC's fixed costs of doing business in India still need to be subtracted from these figures, so available revenue for R&D is likely to be much smaller.

One estimate puts the direct and indirect cost over a ten-year time period of developing a new drug at US$231 million (OPPI, 1994b). Annual profits of US$ 5.2 million would seem quite significant in this context, especially for a low-income country like India and if one allows for the possibility that R&D could be performed less expensively in India. However, the amount of

[35] To convert rupees into U.S. dollars the average 1992 exchange rate from the IMF's International Financial Statistics was used: 25.918 Rs. per US$.

money available for R&D is likely to be smaller than US$ 5.2 million annually. In addition, ciprofloxacin was one of the best selling drugs on the Indian market in 1992. Hypothetical profits are therefore likely to be much smaller for other on-patent chemical entities than in the case of ciprofloxacin. Notwithstanding, one cannot dismiss the possibility that, in the long term, patent protection in India could affect private R&D decisions and contribute to new drug discoveries—especially against diseases particular to developing countries.[36]

Finally, Tables 9 and 10 present the simulated static consumer welfare losses for the two therapeutic groups, which are expressed as compensating variations. As one would expect, welfare losses are smaller the more price-elastic is overall demand in the therapeutic group and the higher the degree of substitutability among chemical entities. The latter effect is relatively more pronounced in the case of hypotensives, because the presence of a larger off-patent market segment makes therapeutic competition more effective.

The figures shown seem very high in relation to TNCs' profits.[37] Taking the case of quinolones, for example, welfare losses on an annual basis range from 744.2 million Rs. (US$ 28.7 million) to 1,810.4 million Rs. (US$ 69.9 million)—again assuming the more realistic $\phi_i = 3.5$. These large figures are due to the properties of the CES sub-subutility function in (3). Specifically, the compensating variations capture not only the traditional deadweight loss due to higher prices, but also the loss in product variety, as far as consumers cannot choose any more among different brands for on-patent chemical entities once patents are introduced.

IX. Summary of main findings

This study has simulated the effects of the introduction of product patent protection on two therapeutic drug groups in the Indian pharmacy market. Such an analysis is of interest as India will have to amend its current patent regime in this regard by 2005 and until then, establish

[36] Currently, only a very small portion of worldwide R&D is spent on diseases prevalent in developing countries and most of it is conducted by publicly-funded organizations or the military in the developed world (see Lanjouw, 1997).

[37] The figures are also much higher than estimated welfare losses in Watal (1998a).

a transitional regime which would allow the filing of patent applications for newly developed drugs and grant exclusive marketing rights to such drugs.

The usefulness of a simulation of overnight patent protection is limited for several reasons. First, the introduction of patent protection for pharmaceutical products as spelled-out in the TRIPS Agreement does not extend to drugs which are already on the market, i.e. there is no obligation for 'pipeline' protection of pharmaceutical products. This implies that the six on-patent drugs examined in this paper indeed will never receive patent protection in India. It is worth emphasizing that the introduction of pharmaceutical product patent protection as required by the TRIPS Agreement will lead neither to actual price increases nor to the direct displacement of Indian imitators. For any newly developed chemical entity, protection applies from the first day on the market.

Second, it was necessary to make strong assumptions on the weight of the TNC's product in the demand function and the TNC's marginal costs of production. The simulation suffered from inadequate data with regard to demand and substitution elasticities. Moreover, the neglect of potential licensing activity may have biased the calibrated and simulated equilibria. Third, it was assumed that all other market conditions remain equal. This is clearly a simplification. For example, stronger patent protection may induce the Indian government to impose price controls or grant compulsory licenses.

These reservations notwithstanding, the simulation highlights some relevant variables that are likely to determine the impact of pharmaceutical patent protection in India on prices, TNC profits, and welfare. Specifically, it clearly demonstrated the relevance of therapeutic competition. The availability of close, off-patent therapeutic substitutes can restrain prices and limit potential welfare losses. To put it differently, if future drug discoveries are mainly new varieties of already existing therapeutic treatments, the impact is likely to be relatively small. If newly discovered drugs are medicinal breakthroughs, however, prices may be significantly above competitive levels and static welfare losses relatively large.

From the viewpoint of TNCs, potential profits depended crucially on the overall price elasticity in the therapeutic group. If demand is highly price-elastic, as one may expect in a low-

income country with limited insurance coverage, TNC profits are likely to be small. However, if one takes into account the possibility that future changes in the Indian health care system, such as the opening of medical insurance provision to private competition (Lanjouw 1997), may reduce the price sensitivity of demand, patent holders' profits could increase substantially.

The lack of reliable estimates for structural model parameters and the wide variations in simulated profit levels precluded an assessment of whether the introduction of patent protection in India will boost R&D activity of transnational corporation and lead to an acceleration in the rate of new drug discovery. In the long run, it is possible that TNCs will do more research on, for example, tropical diseases, given that most developing countries will move toward stronger patent rights in a post-TRIPS world.

From the viewpoint of Indian consumers, the simulated welfare losses in this study were quite large—in part due to a loss in brand variety implied by the CES sub-subutility function. However, it needs to be emphasized that, as of 1993, the patented market segment in India accounted for only 10.9 percent of the total sales values of the Top-500 pharmaceutical products in India. Moreover, the Indian Government will have some flexibility in restraining high prices through the grant of compulsory licenses and price controls—as long as these regulations are in compliance with the TRIPS Agreement.

Appendix

This appendix derives the first order condition (8) that result from firms' profit maximizing behavior. From (4), (5), and (7), we obtain the following implicit demand functions:

$$P = k^{\frac{1}{\varepsilon}} D^{-\frac{1}{\varepsilon}}, \tag{A.1}$$

$$P_i = v_i k^{\frac{1}{\sigma}} P^{\frac{\sigma-\varepsilon}{\sigma}} D_i^{-\frac{1}{\sigma}}, \tag{A.2}$$

$$P_{ij} = v_i^{\frac{\sigma}{\phi_i}} w_{ij} k^{\frac{1}{\phi_i}} P^{\frac{\sigma-\varepsilon}{\phi_i}} P_i^{\frac{\phi_i-\sigma}{\phi_i}} D_{ij}^{-\frac{1}{\phi_i}}. \tag{A.3}$$

Differentiating (A.1) with respect to D, (A.2) with respect to D_i and (A.3) with respect to D_{ij} yields

$$\frac{\partial P}{\partial D} = -\frac{1}{\varepsilon}\frac{P}{D}, \tag{A.4}$$

$$\frac{\partial P_i}{\partial D_i} = -\frac{1}{\sigma}\frac{P_i}{D_i} + \frac{\sigma-\varepsilon}{\sigma}\frac{P_i}{P}\frac{\partial P}{\partial D}\frac{\partial D}{\partial D_i}, \tag{A.5}$$

$$\frac{\partial P_{ij}}{\partial D_{ij}} = -\frac{1}{\phi_i}\frac{P_{ij}}{D_{ij}} + \left[\frac{\phi_i-\sigma}{\phi_i}\frac{P_{ij}}{P_i}\frac{\partial P_i}{\partial D_i} + \frac{\sigma-\varepsilon}{\phi_i}\frac{P_{ij}}{P}\frac{\partial P}{\partial D}\frac{\partial D}{\partial D_i}\right]\frac{\partial D_i}{\partial D_{ij}}. \tag{A.6}$$

The changes in the subutility level and sub-subutility levels can be computed directly from (2) and (3):

$$\frac{\partial D}{\partial D_i} = \frac{v_i D_i^{\frac{\sigma-1}{\sigma}}}{\sum_{z=0}^{n} v_z D_z^{\frac{\sigma-1}{\sigma}}}\frac{D}{D_i} = t_i\frac{D}{D_i}, \tag{A.7}$$

$$\frac{\partial D_i}{\partial D_{ij}} = \frac{w_{ij} D_{ij}^{\frac{\phi_i - 1}{\phi_i}}}{\sum_{z=0}^{m_i} w_{iz} D_{iz}^{\frac{\phi_i - 1}{\phi_i}}} \frac{D_i}{D_{ij}} = s_{ij} \frac{D_i}{D_{ij}}. \tag{A.8}$$

Using these two partial derivatives and substituting (A.4) and (A.5) into (A.6), we can compute the inverse demand elasticity perceived by the firm supplying brand *j*:

$$\frac{\partial P_{ij}}{\partial D_{ij}} \frac{D_{ij}}{P_{ij}} = -\frac{1 - s_{ij}}{\phi_i} - \frac{s_{ij}(1 - t_i)}{\sigma} - \frac{s_{ij} t_i}{\varepsilon}. \tag{A.9}$$

Next, we consider brand *k* of chemical entity *i*, which is supplied by the same firm that supplies brand *j*. Differentiating *k*'s demand function

$$P_{ik} = v_i^{\frac{\sigma}{\phi_i}} w_{ik} k^{\frac{1}{\phi_i}} P^{\frac{\sigma - \varepsilon}{\phi_i}} P_i^{\frac{\phi_i - \sigma}{\phi_i}} D_{ik}^{-\frac{1}{\phi_i}} \tag{A.10}$$

with respect to D_{ij} yields

$$\frac{\partial P_{ik}}{\partial D_{ij}} = \left[\frac{\phi_i - \sigma}{\phi_i} \frac{P_{ik}}{P_i} \frac{\partial P_i}{\partial D_i} + \frac{\sigma - \varepsilon}{\phi_i} \frac{P_{ik}}{P} \frac{\partial P}{\partial D} \frac{\partial D}{\partial D_i} \right] \frac{\partial D_i}{\partial D_{ij}}. \tag{A.11}$$

Using the above partial derivatives, we can compute the inverse cross-demand elasticity:

$$\frac{\partial P_{ik}}{\partial D_{ij}} \frac{D_{ij}}{P_{ik}} = \left[\frac{1}{\phi_i} - \frac{1 - t_i}{\sigma} - \frac{t_i}{\varepsilon} \right] s_{ij}. \tag{A.12}$$

Finally, we consider the brand of chemical entity *l* that is produced by the same firm that supplies brand *j* of chemical entity *i*. Differentiating the demand function

$$P_{l\cdot} = v_l^{\frac{\sigma}{\phi_l}} w_{l\cdot} k^{\frac{1}{\phi_l}} P^{\frac{\sigma - \varepsilon}{\phi_l}} P_l^{\frac{\phi_l - \sigma}{\phi_l}} D_{l\cdot}^{-\frac{1}{\phi_l}} \tag{A.13}$$

with respect to D_{ij} yields

$$\frac{\partial P_{l\cdot}}{\partial D_{ij}} = \left[\frac{\phi_l - \sigma}{\phi_l}\frac{\sigma - \varepsilon}{\sigma} + \frac{\sigma - \varepsilon}{\phi_l}\right]\frac{P_{l\cdot}}{P}\frac{\partial P}{\partial D}\frac{\partial D}{\partial D_i}\frac{\partial D_i}{\partial D_{ij}}, \tag{A.14}$$

which leads to the following inverse cross-demand elasticity:

$$\frac{\partial P_{l\cdot}}{\partial D_{ij}}\frac{D_{ij}}{P_{l\cdot}} = s_{ij}t_i\left[\frac{\varepsilon - \sigma}{\sigma\varepsilon}\right]. \tag{A.15}$$

Now consider profits π_{ij} of the firm that supplies brand j of chemical entity i. These are given by

$$\pi_{ij} = D_{ij}\left(P_{ij} - c_{ij}\right) + \sum_k D_{ik}\left(P_{ik} - c_{ik}\right) + \sum_l D_{l\cdot}\left(P_{l\cdot} - c_{l\cdot}\right). \tag{A.16}$$

Cournot behavior with respect to brand j of chemical entity i leads to the following first order condition:

$$P_{ij} + D_{ij}\frac{\partial P_{ij}}{\partial D_{ij}} + \sum_k D_{ik}\frac{\partial P_{ik}}{\partial D_{ij}} + \sum_l D_{l\cdot}\frac{\partial P_{l\cdot}}{\partial D_{ij}} = c_{ij}. \tag{A.17}$$

Using the demand elasticities in (A.9), (A.12), and (A.15) and the fact that $\sum_z D_{iz}P_{iz} = D_i P_i$, (A.17) can be transformed into condition (8), as stated in the text. It is left to the reader to show that Bertrand behavior leads to the same first order condition.

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Table 1: Quinolones—Overview

Chemical entity	Patent owner	Year of patent expiry	Number of brands in India	Total sales ('000 Rs.)	Weighted average price (Rs.)	Weighted standard deviation of prices
Ciprofloxacin	Bayer AG	2001	37	555,515	17.63	1.23
Norfloxacin	Kyorin & Roger Bellon/Dainippon	1998	24	467,238	4.43	0.63
Pefloxacin	Roger Bellon/ Dainippon	1998	8	125,370	8.92	0.68
Ofloxacin	Daiichi Seiyaku Co.	2001	2	48,778	20.01	0.35
Nalidixic Acid	*(off-patent)*	*(off-patent)*	4	69,260	0.93	0.08

Notes: The patent owners were inactive in the Indian market for all five on-patent chemical entities. Figures are for 1992.

Source: Redwood (1994), Operations Research Group (1992), and The Merck Index (1989).

Table 2: Hypotensives—Overview

Chemical entity	Patent owner	Year of patent expiry	Number of brands in India	Total sales ('000 Rs.)	Weighted average price (Rs.)	Weighted standard deviation of prices
Enalapril maleate	Merck & Co.	1999	14	67,639	1.19	0.12
Captopril	Squibb	1997	5	36,591	2.18	0.10
Nifedipine/ Atenolol	*(off-patent)*	*(off-patent)*	12	66,064	1.70	0.22
Methyldopa	*(off-patent)*	*(off-patent)*	8	56,920	1.59	0.21
Lisinopril	*(off-patent)*	*(off-patent)*	9	10,260	2.46	0.21
Clonidine	*(off-patent)*	*(off-patent)*	2	8,518	0.36	0.06
Indapamide	*(off-patent)*	*(off-patent)*	1	7,609	2.52	*n.a.*
Prazosin	*(off-patent)*	*(off-patent)*	1	3,130	0.92	*n.a.*
Perindopril	*(off-patent)*	*(off-patent)*	1	1,156	16.22	*n.a.*
Hydralazine	*(off-patent)*	*(off-patent)*	1	765	0.07	*n.a.*
Reserpine	*(off-patent)*	*(off-patent)*	1	237	0.13	*n.a.*

Notes: The patent owners were inactive in the Indian market for both on-patent chemical entities. Figures are for 1992.

Source: Redwood (1994), Operations Research Group (1992), and The Merck Index (1989).

Table 3: Quinolones—Calibrated Weight Parameters

	$\phi_i = 3.5$		$\phi_i = 5.5$	
Chemical entity	v_i ($\sigma = 1.1$)	v_i ($\sigma = 2.0$)	v_i ($\sigma = 1.1$)	v_i ($\sigma = 2.0$)
Ciprofloxacin	0.463	0.587	0.464	0.592
Norfloxacin	0.332	0.213	0.333	0.216
Pefloxacin	0.118	0.117	0.118	0.114
Ofloxacin	0.042	0.067	0.042	0.062
Nalidixic Acid	0.044	0.017	0.044	0.017

Notes: Variables are explained in the text. Weights may not exactly sum up to one due to rounding errors.

Table 4: Hypotensives—Calibrated Weight Parameters

	$\phi_i = 3.5$		$\phi_i = 5.5$	
Chemical entity	v_i ($\sigma = 1.1$)	v_i ($\sigma = 2.0$)	v_i ($\sigma = 1.1$)	v_i ($\sigma = 2.0$)
Enalapril maleate	0.259	0.232	0.259	0.232
Captopril	0.142	0.146	0.142	0.145
Nifedipine/Atenolol	0.256	0.247	0.256	0.248
Methyldopa	0.207	0.157	0.208	0.163
Lisinopril	0.052	0.110	0.052	0.110
Clonidine	0.030	0.019	0.029	0.018
Indapamide	0.030	0.035	0.030	0.033
Prazosin	0.012	0.014	0.012	0.013
Perindopril	0.007	0.036	0.007	0.034
Hydralazine	0.002	0.002	0.003	0.002
Reserpine	0.001	0.001	0.001	0.001

Notes: Variables are explained in the text. Weights may not exactly sum up to one due to rounding errors.

Table 5: Quinolones—Average Profit Margins

	$\varepsilon = 1.5$		$\varepsilon = 2.5$	
	$\sigma = 1.1$	$\sigma = 2.0$	$\sigma = 1.1$	$\sigma = 2.0$
$\phi_i = 3.5$	32.1 (40.3)	30.6 (35.4)	31.3 (37.2)	29.7 (32.4)
$\phi_i = 5.5$	22.5 (32.3)	20.9 (27.5)	21.6 (29.2)	20.1 (24.4)

Notes: Sales-weighted averages are in parentheses. Figures are expressed in percentage values.

Table 6: Hypotensives —Average Profit Margins

	$\varepsilon = 1.5$		$\varepsilon = 2.5$	
	$\sigma = 1.1$	$\sigma = 2.0$	$\sigma = 1.1$	$\sigma = 2.0$
$\phi_i = 3.5$	40.3 (54.7)	33.4 (39.7)	39.5 (52.4)	32.6 (37.4)
$\phi_i = 5.5$	32.0 (49.0)	25.0 (34.0)	31.2 (46.7)	24.2 (31.7)

Notes: Sales-weighted averages are in parentheses. Figures are expressed in percentage values.

Table 7: Quinolones—Simulation

	$\varepsilon = 1.5$				$\varepsilon = 2.5$			
	$\sigma = 1.1$		$\sigma = 2.0$		$\sigma = 1.1$		$\sigma = 2.0$	
	Price increase (in %)	TNC profit (in '000 Rs.)	Price increase (in %)	TNC profit (in '000 Rs.)	Price increase (in %)	TNC profit (in '000 Rs.)	Price increase (in %)	TNC profit (in '000 Rs.)
$\phi_i = 3.5$								
Ciprofloxacin	233.5	11,185	45.8	8,171	119.1	1,474	30.8	2,075
Norfloxacin	251.5	9,643	43.2	8,269	140.9	1,303	29.5	2,081
Pefloxacin	353.0	3,400	35.6	4,210	267.6	493	27.3	1,094
Ofloxacin	318.6	1,189	20.6	2,603	308.5	173	21.0	652
$\phi_i = 5.5$								
Ciprofloxacin	276.7	13,845	68.4	11,646	145.7	2,773	45.8	4,155
Norfloxacin	297.9	11,855	63.6	10,968	170.9	2,437	44.4	3,879
Pefloxacin	416.5	4,100	50.6	4,664	319.5	905	41.9	1,694
Ofloxacin	370.5	1,401	30.0	2,312	357.2	311	31.5	811

Notes: The price increase refers to the difference between the TNC's price under patent protection and the weighted average price of all suppliers in the absence of patent protection. The figures for TNC profits are on a monthly basis.

Table 8: Hypotensives—Simulation

	$\varepsilon = 1.5$				$\varepsilon = 2.5$			
	$\sigma = 1.1$		$\sigma = 2.0$		$\sigma = 1.1$		$\sigma = 2.0$	
	Price increase (in %)	TNC profit (in '000 Rs.)	Price increase (in %)	TNC profit (in '000 Rs.)	Price increase (in %)	TNC profit (in '000 Rs.)	Price increase (in %)	TNC profit (in '000 Rs.)
$\phi_i = 3.5$								
Enalapril maleate	285.4	2,807	32.5	909	179.7	1,396	30.0	645
Captopril	142.3	1,676	12.4	860	105.6	849	12.5	600
$\phi_i = 5.5$								
Enalapril maleate	333.0	3,027	49.6	1,260	211.3	1,680	43.7	955
Captopril	166.4	1,780	19.3	1,051	123.9	1,009	18.0	783

Notes: The price increase refers to the difference between the TNC's price under patent protection and the weighted average price of all suppliers in the absence of patent protection. The figures for TNC profits are on a monthly basis.

Table 9: Quinolones—Simulated Consumer Welfare Losses

	$\varepsilon = 1.5$		$\varepsilon = 2.5$	
	$\sigma = 1.1$	$\sigma = 2.0$	$\sigma = 1.1$	$\sigma = 2.0$
$\phi_i = 3.5$	150,867	107,167	68,921	62,015
$\phi_i = 5.5$	135,993	88,185	66,025	55,020

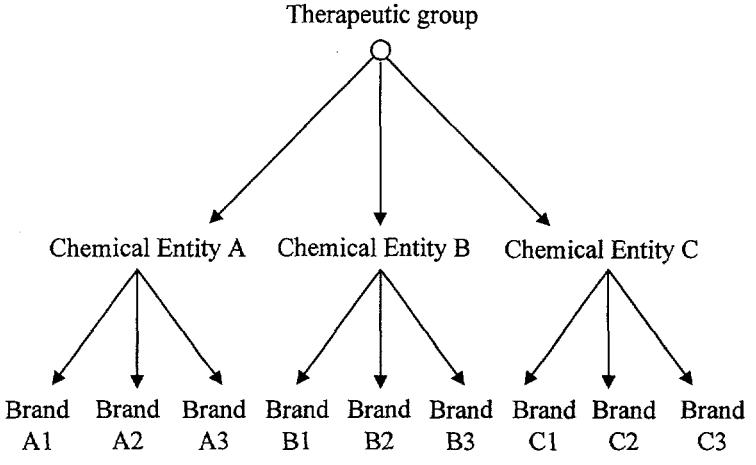
Notes: Figures shown are compensating variations (in thousands of Rupees), i.e. the additional income consumers would need to be as well off after patent introduction as before patent introduction. Figures are on a monthly basis.

Table 10: Hypotensives—Simulated Consumer Welfare Losses

	$\varepsilon = 1.5$		$\varepsilon = 2.5$	
	$\sigma = 1.1$	$\sigma = 2.0$	$\sigma = 1.1$	$\sigma = 2.0$
$\phi_i = 3.5$	14,203	6,413	9,398	5,359
$\phi_i = 5.5$	12,632	5,232	8,486	4,449

Notes: Figures shown are compensating variations (in thousands of Rupees), i.e. the additional income consumers would need to be as well off after patent introduction as before patent introduction. Figures are on a monthly basis.

Figure 1: Pharmaceutical Demand—A Two-Stage Decision-Making Process



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